THE MINISTER OF STATE IN THE DEPARTMENTS OF EDUCATION AND CULTURE IN THE MINISTRY OF HUMAN RESOURCE DEVELOPMENT (SHRI L. P. SHAHI): (a) Yes, Sir.

(b) The technique known as 'Clay Pack' or 'Attapulgite' method involves use of inert clay mixed with solvents applied in pack on the surface to be cleaned. The packs act efficaciously to remove accretions or unwanted substances from the marble surface by a process called adsorption.

Introductory Scrutiny of Drugs and Vaccines for Consumer Safety

985: SHRI DAYANAND SAHAY:

DR. (SHRIMATI) SAROJINI MAHISHI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what steps Government propose to take for closer scrutiny of introduction of new drugs and vaccines for consumer safety;

(b) whether such steps include monitoring of adverse drug reactions, rational therapeutics and good clinical trials;

(c) if so, what are the guidelines on introduction of new drugs and the existing machinery operating; and

(d) whether NDA propose to give adequate inputs and status to the concerned division for discharging the above duties more effectively and if so, by when?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) and (b) Government proposes to make "Guidelines for Introduction of New Drugs" statutory. The guidelines include the various norms to ensure 'Good' clinical investigations of new drugs. A Plan proposal has been drawn up to monitor adverse drug reactions.

(c) The guidelines on introduction of new drugs defines what constitute a 'new drug', the various data on animals that are required to be submitted in relation to its safety and efficacy before a drug could be experimented on human for the first time and the necessary technical information that are required to be generated before a new drug could be allowed to be marketed in the country. The New Drug Division of the Central Drugs Standard Control Organisation, headed by a Medical Pharmacologist, works under the overall supervision of the Drugs Controller (India).

(d) National Drug Authority has not been constituted so far.

Price Control of the Trachoma Drugs under National Health Programme

986. SHRI DAYANAND SAHAY:

DR. (SHRIMATI) SAROJINI MAHISHI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the answer to Unstarred Question 1113 given in the Rajya Sabha on 18th November, 1987 and state:

(a) whether it is a fact that control of Trachoma is one of the programmes under this National Health Programme;

(b) if so, whether it is a fact that as per Drug Policy 1986 which has the approval of all the drugs required for National Health Programmes will be covered under category I of Drugs Price Control Order;

(c) if so, whether Government recommended for inclusion of Polymixin, Fremycetine, Neomycin, Gentamycin, Chlorteraiycline, Vitamin A, Oxytetracycline under category I which are used for Trachoma control programme;

(d) if so, by when these drugs will be included and if not, the reasons therefor; and

(e) the names of other drugs required for Trachoma Control Programme still under consideration for inclusion and by when necessary recommendation will be made?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) There is a comprehensive programme for Prevention of visual impairment and control of blindness which includes control of Trachoma.

(b) For this programme the following drugs have been recommended and included in Category I of Drugs Prices Control order 1987.

1. Tetracycline Hydrochloride
2. Sodium Sulphacetamide
3. Pilocarpine
4. Hydrocortisone
5. Iodoxouridnie
6. Timolol
7. Acetazolamide
8. Atropine
9. Hoamtropin

(c) to (e) These drugs are not exclusively used for Trachoma control. They are used for other disease indications.

Sale of Aspirin without Warning

987. DR. (SHRIMATI) SAROJINI MAHISHI:
SHRI RAJNI RANJAN SAHU:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government's attention has been drawn to the news item that appeared in the Indian Express on 3rd November, 1987 under the heading Pushing Aspirin without proper warning;

(b) whether it is a fact that the Drugs Collector (India) has issued instructions to the formulators of Aspirin to put warning against the use of Aspirin by Children but has allowed the manufacture of Baby Asprin such as Majoral; and

(c) if so, the reasons for such contradictory policy being followed by the authorities?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (c) Following a peculiar adverse reaction to Aspirin in children suffering from viral infections like Chicken Pox reported abroad, popularly knows as "Reyes' Syndrome", the Drugs Controller (India) had directed the manufacturers of Aspirin fomulations in the country to give a warning on the label and cartons "NOT TO BE GIVEN IN CHILDREN BELOW 12 YEARS OF AGE EXCEPT UNDER MEDICAL ADVISE".

The news media highlighted that some of Aspirin formulations do not bear such warning. Promptly a survey was made by the Drugs Controller (India) whether the desired warning required to be incorporated was given or not. The survey reports indicate that manufacturers of Aspirin formulations including Majoral do give such warning.

Cobalt Therapy

988. SHRI BIR BHADRA PRATAP SINGH:
SHRI BHAGAT RAM MANHAR:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the reply to the Unstarred Question 2260 given in the Rajya Sabha on the 16th March, 1988 and state:

(a) what are the names of hospitals using cobalt therapy units and when each one of them installed it;